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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,081	12/28/2001	Colin Chong	047711-0284	1999

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EXAMINER

LAM, ANN Y

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 06/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/036,081	<b>Applicant(s)</b> CHONG ET AL.	
	<b>Examiner</b> Ann Y. Lam	<b>Art Unit</b> 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-4, 8-24, 44, 47-52, 55-57 and 59-78 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 8-24, 44, 47-52, 55-57, 59-78 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

*AS*

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1-3, 8-10, 13-17, 19, 22, 44, 47-50, 55-57, 59-62, 65-69, 71, 72 and 75-78 are rejected under 35 U.S.C. 102(e) as being anticipated by Sherry, 6,358,238.

As to claims 1, 8, 9, 10, 13, 19, 48-50, 55, 60-62, 65, 71, Sherry discloses a first layer and a barrier layer circumferentially adjacent to the first layer, wherein the first layer and the barrier layer are configured to define a tubular structure and wherein the barrier layer (i.e., outer layer, or alternatively inner layer) is configured to provide a barrier to the diffusion of CO<sub>2</sub> (col. 5, lines 18-19, and 21-22.) PTFE, i.e., polytetrafluorethylene, and nylon are disclosed and claimed by Applicant as having a permeability lower than polyethylene for CO<sub>2</sub> and phenolic compounds.

As to claims 2, 3, 56, 57, Applicant claims that the second material has a permeability lower than polyethylene for CO<sub>2</sub> or phenolic compounds, and Applicant claims two different embodiments, wherein one embodiment has the first layer on the

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outside and another embodiment wherein the first layer is on the inside. However, both claimed embodiments are anticipated by Sherry since Sherry discloses that both the first and second layer comprises a material that has a permeability lower than polyethylene for CO<sub>2</sub> and phenolic compounds.

As to claims 14, 66, the inner surface of the first layer substantially covers an outer surface of the second material (see fig. 2)

As to claims 15, 16, 67 and 68, the disclosed reinforcement structure (22) at the distal tip in column 5, lines 16-21, is considered the first layer, and the barrier layer is the inner layer of PTFE.

As to claims 17, 69, an interior layer (i.e., the interior layer of the first material) contacts an inner surface of the barrier layer, the interior layer comprising a substance that is considered to be capable of regulating an interaction of substances with the interior layer.

As to claims 22, 44, 47 and 72, an infusion pump (syringe) is disclosed at column 4, line 38. The syringe is considered to have a sensing device (means for pumping) for regulating the delivery of a formulation.

As to claim 59, polytetrafluorethylene and nylon has a permeability lower phenolic compounds, including phenol and m-cresol.

As to claims 75-78, the barrier layer has sufficient rigidity and density to inhibit expansion of the tubular structure due to pressure within the tubular structure.

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2. Claims 1, 3-5, 11-14, 17, 19, 22, 23, 24, 44, 47, 51-53, 55, 56, 58, 59, 63-66, 69 and 71-78 are rejected under 35 U.S.C. 102(e) as being anticipated by Barry et al., 6,663,606.

Barry discloses a multi-layer catheter (col. 5, line 5) having a first and second layer, wherein the first layer or barrier layer (glass or diamond coating) has a permeability lower than polyethylene for CO<sub>2</sub> or phenolic compounds (col. 7, lines 20 and 24.) Glass and diamond coatings are disclosed and claimed by Applicant as having a permeability lower than polyethylene for CO<sub>2</sub> and phenolic compounds. An infusion pump is disclosed at column 5, line 30. As to claims 23 and 73, the first layer is plastic lumen disclosed in column 9, line 46. As to claim 47, a sensing device for regulating the delivery of formulation is the pumping means of syringe (col. 9, line 46.)

As to claims 75-78, the barrier layer has sufficient rigidity and density to inhibit expansion of the tubular structure due to pressure within the tubular structure.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 18 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sherry, 6,358,238, in view of Bardsley et al., 6,004,310.

Sherry discloses the invention substantially as claimed (see above), except for the interior layer contacting an inner surface of the barrier layer, wherein the interior layer comprises a substance that is hydrophilic. Bardsley teaches a hydrophilic coating on the inside of a catheter lumen in order to improve frictional properties between a guidewire and the lumen of the catheter (col. 8, line 66 – col. 9, line 6.) It would have been obvious to one of ordinary skill in the art to provide a hydrophilic coating as taught by Bardsley in the Sherry lumen, such coating providing the advantage of decreasing friction between a guidewire passing through a catheter.

4. Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sherry, 6,358,238, in view of Nita et al., 5,916,192.

Sherry discloses the invention substantially as claimed (see above), except for an outer diameter of the distal end being constant across the flared shape of the inner diameter of the distal end. Nita discloses a catheter have such a distal tip, in order to cut or separate obstructive matter and aspirate the debris through the catheter (col. 7, lines 3-10.) It would have been obvious to one of ordinary skill in the art to provide a distal tip as taught by Nita in the Sherry multi-layer catheter, such tip providing the advantage of cutting matter to be aspirated through the catheter.

### ***Response to Arguments***

Applicant's arguments filed March 15, 2005 have been fully considered but they are not persuasive.

In response to applicant's argument that Sherry does not disclose configuring a barrier layer to provide a barrier to the diffusion of CO<sub>2</sub>, and that Sherry does not describe or suggest the gas permeability of PTFE Teflon with respect to CO<sub>2</sub> (pages 12-14 and 16 in Applicant's response), a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). In this case, Sherry discloses the claimed material, and the materials are capable of performing the intended use, that is, the materials are capable of providing a barrier to the diffusion of CO<sub>2</sub>. Furthermore, those materials are described in Applicant's specification as having those properties.

Applicant also argues that claim 20 has been amended to recite that the tapered shape has a narrow end at the distal end. This argument is moot since the basis for rejection of claim 20 has been changed as described in the above rejection.

Applicant also argues on pages 1-14 that claim 74 recites that "the tubular structure is configured to inhibit expansion due to pressure within the tubular structure".

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Applicant argues that the end portion of the Sherry catheter expands in diameter upon the application of pressure to the lumen of the catheter. Examiner asserts that the Sherry structure is capable of inhibiting expansion due to pressure within the tubular structure. (The structure and material of the Sherry tube will inhibit expansion depending on how much pressure is within the tubular structure.)

Applicant also argues on page 15 that Barry does not describe or suggest using a barrier layer configured to provide a barrier to the diffusion of CO<sub>2</sub>. Examiner reasserts that Applicant is claiming a device and that the Barry device is capable of performing the intended use. Barry discloses the claimed material, and the materials are capable of performing the intended use, that is, the materials are capable of providing a barrier to the diffusion of CO<sub>2</sub>. Furthermore the materials are described in the specification as having this property.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of



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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L. 

  
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05/31/05